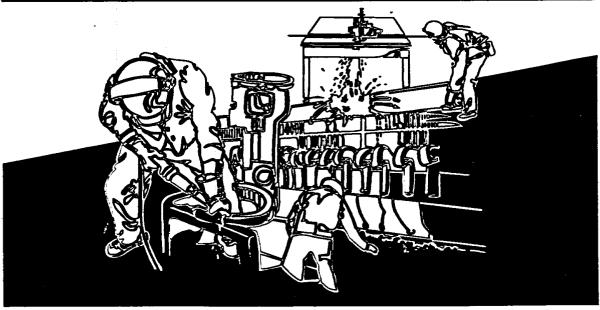


NIOSH HEALTH HAZARD EVALUATION REPORT







U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health



PREFACE

The Hazard Evaluations and Technical Assistance Branch of NIOSH conducts field investigations of possible health hazards in the workplace. These investigations are conducted under the authority of Section 20(a)(6) of the Occupational Safety and Health Act of 1970, 29 U.S.C. 669(a)(6) which authorizes the Secretary of Health and Human Services, following a written request from any employer and authorized representative of employees, to determine whether any substance normally found in the place of employment has potentially toxic effects in such concentrations as used or found.

The Hazard Evaluations and Technical Assistance Branch also provides, upon request, medical, nursing, and industrial hygiene technical and consultative assistance (TA) to federal, State, and local agencies; labor; industry; and other groups or individuals to control occupational health hazards and to prevent related trauma and disease.

Mention of company names or products does not constitute endorsement by the National Institute for Occupational Safety and Health.

HETA 94-0198-2443 AUGUST 1994 RUBBERMAID, INC. WOOSTER, OHIO NIOSH INVESTIGATORS: NANCY CLARK BURTON, MS, CIH DOUGLAS TROUT, MD, MHS

I. SUMMARY

In March 1994, the National Institute for Occupational Safety and Health (NIOSH) received a health hazard evaluation request from the management of Rubbermaid, Inc. in Wooster, Ohio, concerning potential work-related health effects among employees working in the Blow Mold (BM) and Plastics 1 (P1) departments. The reported symptoms included skin rash, facial swelling, and upper respiratory irritation. In response to this request, NIOSH personnel conducted a site visit at the Rubbermaid plant on March 21-22, 1994. During this site visit, NIOSH investigators reviewed current work practices, engineering controls, material safety data sheets (MSDSs), and company medical records. Industrial hygiene sampling conducted included area samples for volatile organic compounds (VOCs) and respirable dust, as well as bulk samples for qualitative analysis of organic compounds.

On the evening of March 21, 1994, after production began, NIOSH staff observed three employees develop skin reactions while making black garbage cans in the BM department. Two of these affected individuals had raised, red lesions on areas of unexposed skin, consistent with the wheals of an urticarial reaction. One of these two developed this reaction after working on BM machine 7 for five minutes, the other after working for one hour on the same machine. The third person had a flat, red rash on the flexor surface of the right forearm. Interviews conducted with employees of the BM and P1 departments revealed reports of a spectrum of health effects, including irritation of the upper airways, swelling and redness of the face, and skin irritation on the hands and forearms. Review of medical records revealed that seven employees had at least one visit to the nursing department for allergic reactions while working with the black garbage cans.

Review of the ventilation system revealed that there was no mechanical ventilation system in the BM department and little air movement. All of the thermal desorption tubes used to detect VOCs contained propane, limonene, and C₁₀-C₁₆ aliphatics. The respirable dust levels were below the analytical limit of detection. The bulk sample analysis of Irganox B-900° antioxidant found unexpected nitrogen compounds (primarily an amine) and di-tert-butyl substituted phenols. Review of the MSDS for Irganox B 900° revealed that three of 183 subjects exposed to Irganox 1076° (a component of Irganox B 900°) exhibited sensitization reactions.

A small number of employees developed skin reactions to an agent used in the production of black garbage cans at this facility. It appears that the antioxidant, breakdown products of the antioxidant, or contaminants in the antioxidant may be the cause of these reactions. Substitution with another antioxidant should be considered. Recommendations regarding ventilation to reduce levels of exposure to materials generated during production in the BM department are offered in Section IX of this report. Even with improved ventilation control, employees demonstrating skin reactions should not work in those areas known to initiate or exacerbate their condition.

KEYWORDS: SIC 3089 (Plastic Products, Not Elsewhere Classified), urticarial reactions, polyethylene, carbon black, Irganox B 900° antioxidant, limonene.

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II. INTRODUCTION

In March 1994, the National Institute for Occupational Safety and Health (NIOSH) received a request for a health hazard evaluation (HHE) from the management of the Rubbermaid, Inc. plant in Wooster, Ohio. The request concerned potential work-related health effects among employees working in the Blow Mold (BM) and Plastics 1 (P1) departments. Specific employee symptoms noted in the request included skin rash, facial swelling, and upper respiratory irritation.

In response to the HHE request, NIOSH personnel conducted a site visit at the Rubbermaid plant on March 21-22, 1994. This report discusses the details of the site visit and presents our findings and recommendations, some of which were presented in an interim letter dated May 6, 1994.

III. BACKGROUND

The Rubbermaid plant in Wooster manufactures a variety of plastic household products. The BM department employs approximately 120 persons and produces molded plastic products such as food containers and garbage cans. In January and February 1993, about 15 employees in the BM department reported intermittent symptoms of sore throats and skin irritation. These symptoms were not identified as being directly related to a particular process or agent. In October 1993, an employee in the BM department reported a rash and lightheadedness when sweeping around one of the BM machines using evergreen color. In the following months, this same person had several other instances of rash when working on the machine making black garbage cans. Beginning in January 1994, nine other persons reported symptoms of rash, facial swelling, and throat tightness when working on machines making black garbage cans (BM department) or black handles (P1 department). During this time, the company had the raw materials used for making black cans and handles analyzed using gas chromatography-mass spectrometry (GC/MS) and found no agents suspected of causing these symptoms. The black can and black handle manufacturing processes had been shut down prior to the NIOSH site visit due to the employees' symptoms.

IV. PROCESS DESCRIPTION

The automated BM machine operates as follows. Black color (4%) and regrind material (96%) are added to a hopper at the top of the machine and then enter a gravity screw-fed conveyor. The black color has three components: polyethylene, carbon black, and Irganox B 900° antioxidant. The material is then heated to 420°F (215°C) and is forced into a diehead. The material is pushed out of the diehead opening and a clamp is attached to the polyethylene material. Air is blown into the plastic and the material inflates to fill the mold cavity. The air is then exhausted from the mold interior and the shaped plastic exits the machine on a conveyor system.

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The garbage cans are produced two at a time from a BM machine. The operator removes the flash and separates the lid from the body of the can. Wheels and handles are added and the cans are packed in cardboard boxes for shipping. There are six BM machines located in this area of the BM department. Five of these were operational at the time of the site visit. The BM machinery exhausts were located at floor level and exhausted directly into the department. There was no mechanical ventilation in the BM area; fresh air was supplied through the loading dock doors.

The black handles for the black garbage cans are made in the P1 department. The process uses the same black color and, in addition, utilizes a blowing agent which adds carbon dioxide (CO₂) bubbles to take up space. The blowing agent is composed of pro-flo carrier resin, dihydroxyaluminum sodium carbonate, sodium bicarbonate, citric acid, and sodium carbonate. Color, regrind material, blowing agent, and virgin resin are added to the top of the molding machine using a hopper. The handles are formed at 400°F (204°C) and are extruded onto a conveyor belt. The conveyor belt carries the handles to a table. There, the employee picks up the handles while they are still hot and packs them in boxes. The teal garbage can handles are made in the same manner except that a different colorant is used. P1 had ceiling exhaust fans and a replacement air unit that supplies unconditioned outside air.

V. METHODS

On March 21, 1994, NIOSH personnel met with management and union representatives in an opening conference. Following this meeting, walk-through surveys of the BM and P1 departments were conducted. Throughout the site visit, NIOSH investigators identified potential workplace exposures by reviewing the production processes and material safety data sheet (MSDS) data, observing employee work practices, and evaluating maintenance activities and engineering controls. At approximately 7:00 p.m., the BM department began making black garbage cans, and the P1 department started making black handles. These processes were run at this time so that the NIOSH investigators could observe the specific processes in question.

Industrial Hygiene

Since we anticipated that levels of contaminants would be low at this facility, 12 thermal desorption tubes were used to collect area air samples in the vicinity of BM Machine 7 (black garbage can line), the black garbage can handle molding machine, and the teal garbage can handle molding machine (for comparison). The thermal desorption tubes were submitted for qualitative analysis of volatile organic compounds (VOCs) using GC/MS. Six bulk samples of the product components were also collected and submitted for qualitative analysis of constituents using GC/MS. The bulk samples were heated to the process temperature (420°F [215°C]) for five minutes and the substances which off-gassed were analyzed.

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Three area air samples for respirable dust were collected in the vicinity of BM Machine 7. These samples were submitted for gravimetric analysis according to NIOSH Method 0600¹ with the following modifications: (1) the filters and back-up pads were stored in an environmentally controlled room for several days to obtain stabilization. The samples were weighed 5-10 minutes apart since the filters had been room stabilized for several days; (2) the back-up pads were not vacuum desiccated; and (3) the samples were not vacuum desiccated 15 minutes prior to final weighing. The analytical limit of detection (LOD) was 0.02 milligrams (mg), which is equivalent to a minimum detectable concentration (MDC) of 0.04 milligrams per cubic meter (mg/m³), assuming a sample volume of 464 liters. Chemical smoke was used to determine airflow patterns in the BM department.

Medical

The NIOSH medical investigators conducted interviews with ten employees in the BM and P1 departments, including all those present who had been previously identified as having health problems associated with making the black garbage cans and handles. The first-aid logs for 1993 and 1994 were reviewed with the occupational nursing staff, as were the accident reports and emergency department records for employees who had reported health problems associated with working in the BM or P1 departments.

VI. EVALUATION CRITERIA

To assess the hazards posed by workplace exposures, NIOSH investigators use a variety of environmental evaluation criteria. These criteria propose exposure levels to which most employees may be exposed for a normal working lifetime without adverse health effects. These levels do not take into consideration individual susceptibility, such as pre-exiting medical conditions, or possible interactions with other agents, or environmental conditions. Evaluation criteria for chemical substances are usually based on the average personal breathing zone exposure to the airborne substance over an entire 8- to 10-hour workday, expressed as a time-weighted average (TWA).

The primary sources of evaluation criteria for the workplace are: NIOSH Criteria Documents and Recommended Exposure Limits (RELs),² the American Conference of Governmental Industrial Hygienists' (ACGIH) Threshold Limit Values (TLVs),³ and the Occupational Safety and Health Administration (OSHA) Permissible Exposure Limits (PELs).⁴ Evaluation criteria change over time with the availability of new toxicologic data.

The OSHA PELs reflect the economic feasibility of controlling exposures in various industries, public notice and comment, and judicial review; whereas the NIOSH RELs are based primarily on concerns related to the prevention of occupational disease. An additional complication is the Court of Appeals decision that vacated the OSHA 1989 Air Contaminants Standard (AFL-CIO v OSHA,

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965F.2d 962 [11th cir., 1992]); OSHA is now enforcing the previous 1971 standards.⁴ However, some states which have OSHA-approved State Plans will continue to enforce the more protective 1989 limits. NIOSH encourages employers to use the 1989 limits or the RELs, whichever are lower.

A variety of VOCs were detected on the thermal desorption tubes. Table 1 lists the major compounds detected, potential health effects, and current evaluation criteria. Several of the detected compounds have no published exposure criteria or toxicological data available at this time and are not included in the table.

Occupational Skin Disorders

Occupational skin diseases account for a large percentage of all occupational illnesses; approximately 80 - 90% of these skin diseases may be classified as contact dermatitis. In general, urticarial reactions make up a small percentage of occupational skin diseases relative to contact dermatitis. Urticaria is a transient vascular reaction of the skin that leads to an accumulation of fluid and localized swelling of dermal tissue surrounded by an erythematous (reddened) flare. Urticarial reactions fall in the type I (immediate, antibody mediated) class of hypersensitivity (allergic) reactions. The localized urticarial lesions are referred to as "wheals" or "hives." Urticaria may also be accompanied by angioedema, which is the swelling of deeper layers of skin including the subcutaneous tissue. Angioedema occurring in the upper respiratory tract may be life-threatening since it can block the airway.

Sensitization refers to the process of developing an allergic reaction to a specific substance. The condition of hypersensitivity becomes established over a period of days to months, and subsequent exposure to even small amounts of the sensitizing (allergenic) material is likely to produce a reaction.

Urticaria may be provoked by a large number of substances, via four basic mechanisms: (1) nonallergic; (2) allergic; (3) combined allergic and nonallergic; and (4) combined allergic eczematous and urticarial.⁶ Nonallergic urticaria reactions occur in most, or almost all, individuals exposed to the causative agent; allergic contact urticaria occurs in individuals who have previously become sensitized to the causative agent. Urticaria related to occupational exposures is usually caused by inhalation of an allergenic material.⁷

VII. RESULTS

Industrial Hygiene Sampling

All 12 thermal desorption tubes contained propane, limonene, and C_{10} - C_{16} aliphatics. Benzaldehyde and citraconic anhydride (a possible decomposition product of citric acid) were detected on the thermal tubes collected in the black handle area. Other compounds detected on most samples included toluene, hexane, C_4 - C_5 alkanes, ethylene glycol butyl ether (EGBE), xylenes,

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tetrahydrofuran, 1,1,1-trichloroethane, acetone, methyl ethyl ketone, freons, ethanol, and styrene. The results from the thermal desorption tubes are qualitative and cannot be compared to occupational evaluation criteria. However, based on the low levels detected, it is unlikely that the workplace concentrations of these compounds would exceed these guidelines. The chromatographs for the thermal desorption tubes are included in Appendix A.

The bulk sample analysis of Irganox B-900° antioxidant found unexpected nitrogen compounds (primarily an amine such as dibutyl formamide) and di-tert-butyl substituted phenols, which are probably decomposition products of the Irganox 1076 component. Additional compounds that were found were 2-butanol, xylenes, and a di-tert-butyl quinone. Some of the same compounds were detected in the black color bulk sample, which also contained alkenes. The chromatographs for the bulk sample analyses are included in Appendix B.

The primary components of the black and teal regrind were C_8 - C_{20} alkenes. Groups of C_3 - C_{20} aliphatics, acetone, t-butanol, and a benzoic acid ester were the major compounds in the headspace analysis of the black handle virgin material. The primary components from the blowing agent were furandiones (citric acid decomposition/rearrangement products) and small amounts of acetone, t-butanol, and aliphatics.

Respirable dust concentrations in the three area air samples were below the minimum detectable concentration of 0.04 mg/m³. Using chemical smoke, NIOSH investigators observed that the BM department was under negative pressure compared to the outside, and there was little or no air movement around the employees or machinery.

MSDS Review

Review of the MSDSs revealed that the anti-oxidant used in making the black and evergreen garbage cans, Irganox B 900°, is composed of octadecyl 3,5-di-tert-butyl-4-hydroxyhydrocinnamate and tris(2,4-di-tert-butylphenyl) phosphite. The MSDS for Irganox B 900° also reports that three of 183 subjects exposed to Irganox 1076° (a component of Irganox B 900°) exhibited nonspecific sensitization reactions. Appendix C contains a summary of these studies, obtained from the manufacturer.

Although we have not found literature directly concerning the specific cinnamate and phosphite compounds in Irganox B 900°, there is information concerning related compounds and dermatologic reactions. Triphenyl phosphite has been reported to cause allergic contact dermatitis. Cinnamic acid is known to be a cause of nonallergenic urticaria (it will generally cause urticarial reactions among most persons exposed), and a related compound, cinnamic aldehyde, has been reported to be both a contact urticarant (via a non-allergic mechanism) and a sensitizer, causing allergic contact dermatitis. Several other reports have noted dermatitis secondary to exposure to cinnamates and related compounds. 10-12

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Specific additives to plastics – butylhydroxytoluene (BHT) and oleylamide – have been reported to cause urticaria via an allergic mechanism, but are not known to be present in the process at Rubbermaid.

Medical

During the site visit, NIOSH staff observed three individuals develop skin reactions while working on BM 7 (the specific machine which was making the black garbage cans). Two of these persons had raised, red lesions on areas of unexposed skin, consistent with the wheals of an urticarial reaction. One of the two developed this reaction after working on BM 7 for five minutes, the other after working for one hour. The third person had a flat, red rash on the flexor surface of the right forearm; this person had not previously reported such symptoms to management or the nursing department.

The interviews conducted with employees of the BM and P1 departments revealed reports of a spectrum of health effects. Four employees in the P1 department reported irritation of the upper airways when breathing in furnes from the black handles as the handles came out of the machine. Three of these also reported swelling and redness of the face, but no other rashes elsewhere, when exposed to the same furnes. One employee in the BM department reported working with the black garbage cans many times previously, but only developing a rash on the hands and forearms the last time the employee worked with the black cans. On the day we interviewed this worker, the employee was performing duties in the vicinity of the black garbage can line but had no symptoms.

Review of the first aid logs and accident reports revealed that seven employees have had at least one visit to the nursing department after experiencing apparent allergic reactions to some substance in the process of producing the black garbage cans. Several of these employees had emergency room records, and one person had been referred to the Cleveland Clinic prior to our visit. Two of these seven persons were the employees who were observed to have unticarial reactions at the time of our site visit.

VIII. DISCUSSION/CONCLUSIONS

At least seven employees in the BM and P1 departments reported experiencing a variety of symptoms related to exposure to the process of producing garbage cans (black and possibly evergreen colors) and black handles. The symptoms include urticarial skin reactions (observed among two employees) in addition to irritant types of effects. The urticarial reactions observed by NIOSH investigators were consistent with allergic/sensitization reactions. The antioxidant used in making these products, Irganox B 900°, contains substances related to known allergens and irritants. In addition, our analysis of the antioxidant has revealed that nitrogen compounds were given off after a bulk sample was heated to a temperature similar to that of the production process. Limonene was found on all

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12 thermal desorption tubes; it is known to be a skin irritant and sensitizer but has not been associated with the other symptoms reported by the workers.

Therefore, although we are unable to identify a specific agent as the cause of the symptoms experienced at this plant, it appears that the antioxidant itself, breakdown products of the antioxidant, or contaminants in the antioxidant are the most likely sources of the workers' symptoms, including in some cases allergic/sensitization reactions. The low levels of other VOCs detected indicated that they are unlikely to be the cause of the adverse health effects experienced by workers at Rubbermaid.

IX. RECOMMENDATIONS

The following recommendations are offered to reduce workers' exposures to the agents which have the potential to produce symptoms in the BM and P1 areas of this plant. NIOSH and OSHA recommend that substitution and engineering controls be used to control hazards to the extent feasible, followed by work practices, and, if necessary, personal protective equipment.

Recommendations regarding ventilation are offered to reduce levels of exposure to materials generated during production in the BM department since there is currently no mechanical ventilation system. Even with improved ventilation control, persons who are already sensitized to the (presently unknown) sensitizing agent(s) should not continue to work in any areas where further exposure to those processes which have caused symptoms in the past may occur.

- 1. Because of the number of persons having symptoms when working on the lines producing black garbage cans and black handles, and the potential seriousness of these medical conditions, we recommend that these lines not operate until the exposure(s) causing these symptoms have been eliminated.
- 2. Use of another antioxidant instead of Irganox B 900° should be considered. If the use of Irganox B 900° continues, further studies are necessary to determine the toxicity of the compound. Further studies may include working with dermatologists to attempt to determine the cause of the urticaria and other skin reactions, as well as determining the nature and the prevalence of the nitrogen compounds identified in the bulk sample of Irganox B 900°.
- 3. To reduce employee exposures to airborne compounds which may be emitted by the BM machines, local exhaust ventilation with replacement (make-up) air should be used in the Blow Mold department. It is important to provide replacement air since the actual exhaust flow rates will be less than the design values because the BM department was under negative pressure relative to the outdoors. Suggestions for the BM cutting station include the addition of side draft hoods to capture the emissions at their source and prevent them from entering the worker's breathing zone. It

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would also be practical to install side draft hoods along the conveyor where the product exits the machine to prevent the off-gassing material from entering the general facility air. These hoods should have minimum slot and duct velocities of 2000 feet per minute (fpm).¹⁴ The BM machine exhausts should be ducted directly outside to avoid recirculating contaminants throughout the facility. The volume of exhausted air would determine the volume of replacement air needed.¹⁴

- 4. A log of all skin reactions should continue to be kept in the medical department to help identify potential causative agents.
- 5. Workers should be educated about the effects of the chemicals they work with and the types of work practices that will minimize their exposure to chemicals. The educational activities should include the identification of work activities where exposures are likely and the recognition of early signs and symptoms of skin reactions.

X. REFERENCES

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- 1. Rubbermaid, Inc., Wooster, Ohio
- 2. United Rubber Workers Union, Local 302, Wooster, Ohio
- 3. International United Rubber Workers Union, Akron, Ohio
- 4. OSHA, Region V, Chicago, Illinois

For the purpose of informing affected employees, copies of this report shall be posted by the employer in a prominent place accessible to the employees for a period of 30 calendar days.

Toxicology and Evaluation Critaria for Selected Volatile Organic Compounds Rubbermaid, inc.
Wooster, Ohio
HETA 94-0198 Teble 1

Compound	. Health Effects ¹⁰	NIOSH REL (ppm- parts per million) ¹⁰	OSHA PEL ¹²	ACGIH TLV11
Acetone	Central nervous system (CNS) depression; eye, nose, throat, and skin irritation.	250	1000	750
t-Butanol	CNS effects.	100	100	100
Ethylene Glycol Butyl Ether (EGBE)	Adverse effects on blood and the blood cellforming system, tissue irritation, CNS depression.	8 0		
Ethenol*	Eye, respiratory, and skin irritation.	1000	1000	1000
Hexane	Skin and nervous system effects.	50	500	50
Limonene	Mild skin irritation and skin sensitization.	•		
Methyl ethyl ketone	Irritation, liver, kidney, and CNS effects.	200	200	200
Propane	Asphyxiation.	1000	1000	Simple Amphyxiant
Styrene	Nervous system effects, eye and respiratory irritation, reproductive effects	50	100	50
Tetrahydrofuran	Anesthetic effects, respiratory tract irritation.	200	200	200
Toluene	CNS depression.	100	200	50
1,1,1- Trichloroethane	CNS, liver, and cardiovascular effects.	350	350	350
Xylenes	CNS depression, respiratory and eye irritation.	100	100	100

* Ingestion of ethanol in pregnant women has been associated with fetal abnormalities.

Appendix A

SEQ 8002 THERMAL DESCRPTION TUBES PEAK IDENTIFICATION

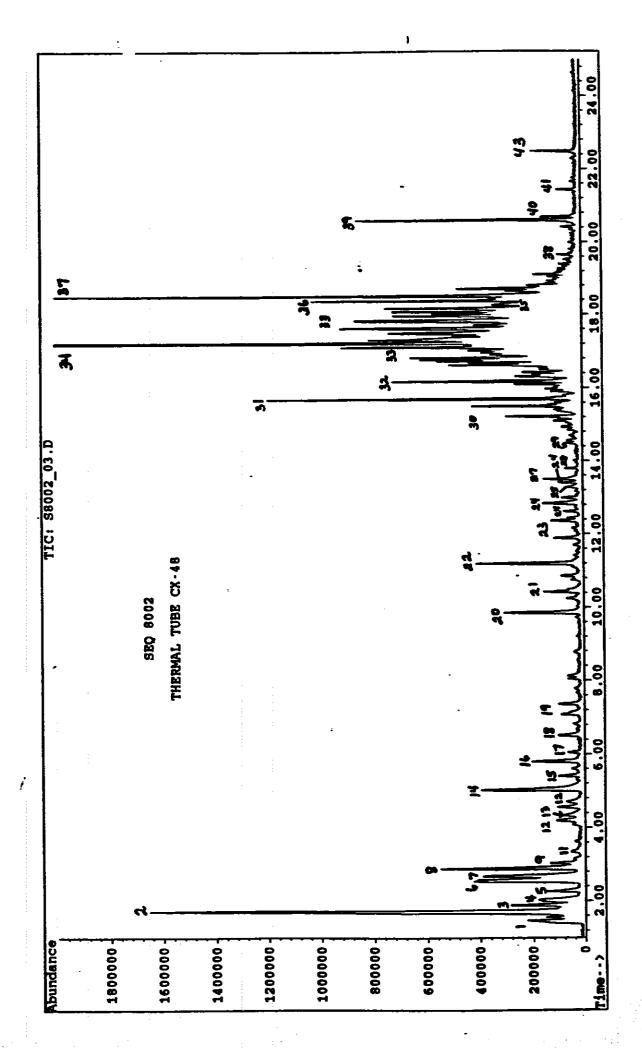
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fluoromethane
8) Pentane
9) t-Butanol
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20) Toluene
21) C.H. /C.H. aliphatics
22) n-Octane
avi m_ocrane

23) C,H₁₀/C,H₂₀ aliphatics 24) Xylene/ethyl benzene isomers 25) Styrene 26) Tylene isomer plus citraconic anhydride? (decomposition product of citric acid?) 27) Butyl cellosolve 28) n-Nonane 29) Benzaldehyde 30) C10H20/C10H22 aliphatics 31) n-Decane plus trace pdichlorobenzene 32) Limonene 33) C₁₁-C₁₂ aliphatics 34) n-Undecane 35) Trace t-butyl phenol 36) Dodecene 37) Dodecane 38) Tridecane 39) Tetradecene 40) Tetradecane 41) C14H29O2, 2,6-ditert-butylquinone 42) Ethoxy ethyl benzoate 43) Hexadecene

44) Octadecene

*Also present on some field/media blanks.

BLOW MOLDING — FLASH CUTTING RUBBERMAID, INC. HETA 94-0198



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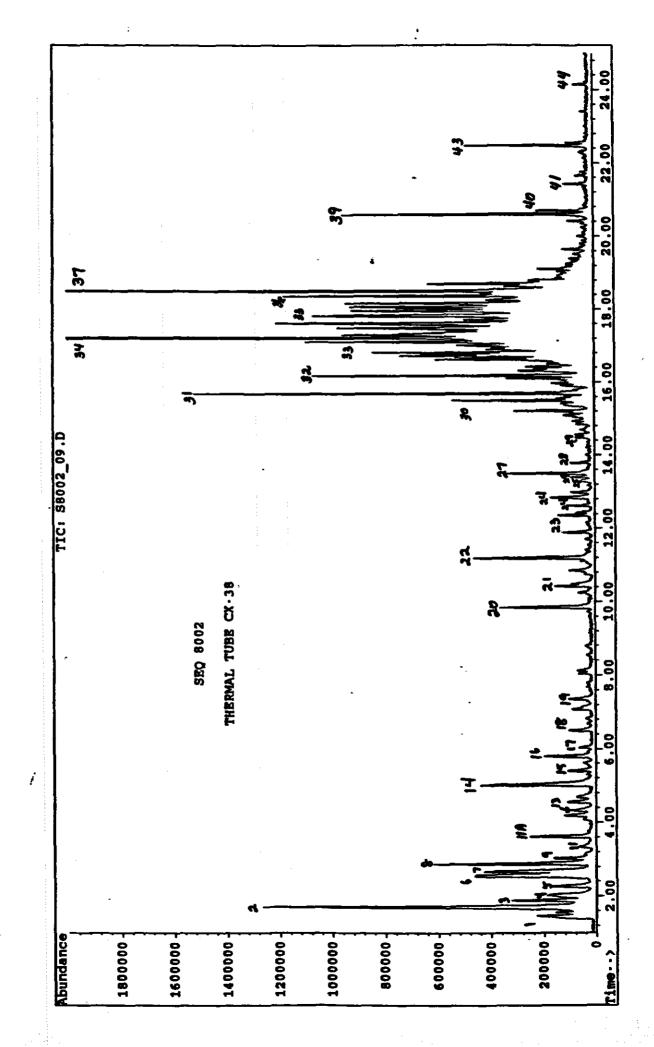
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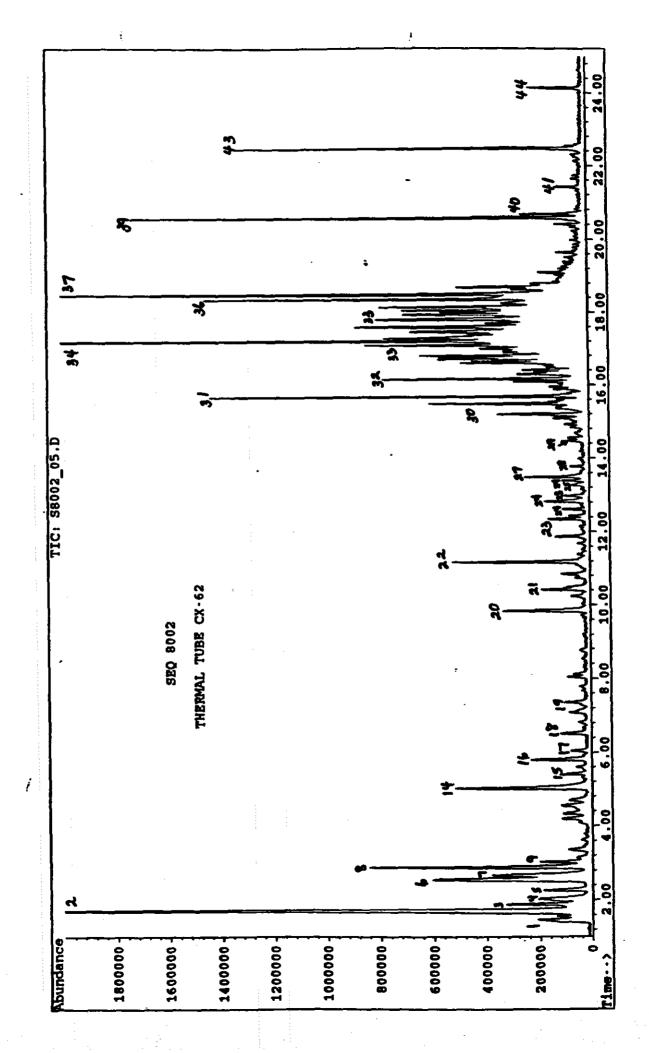
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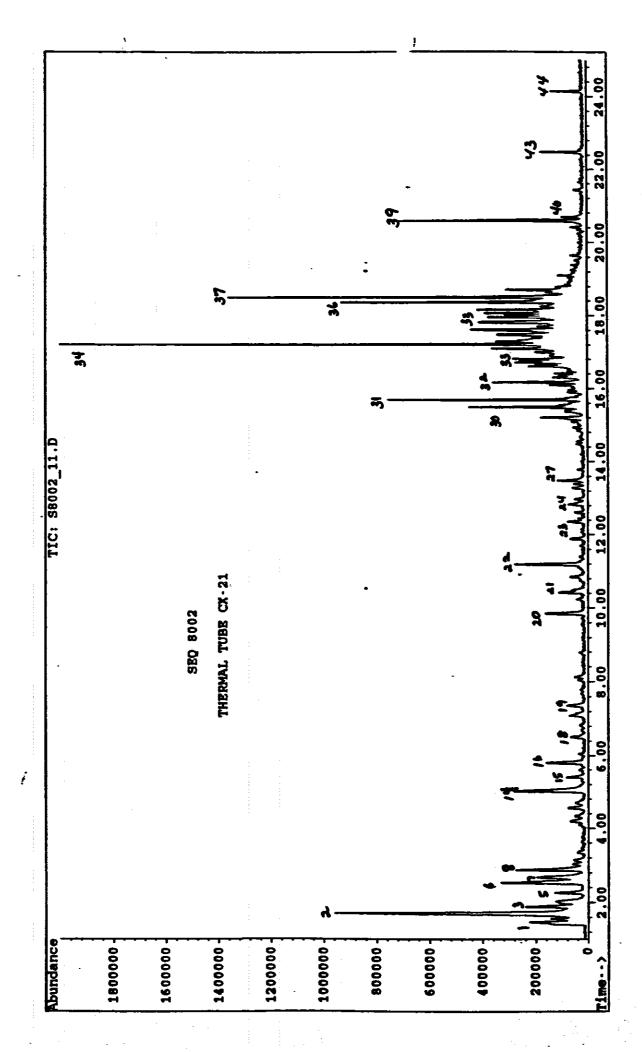
BLOW MOLDING --- CAN CONVEYOR RUBBERMAID, INC. HETA 94-0198



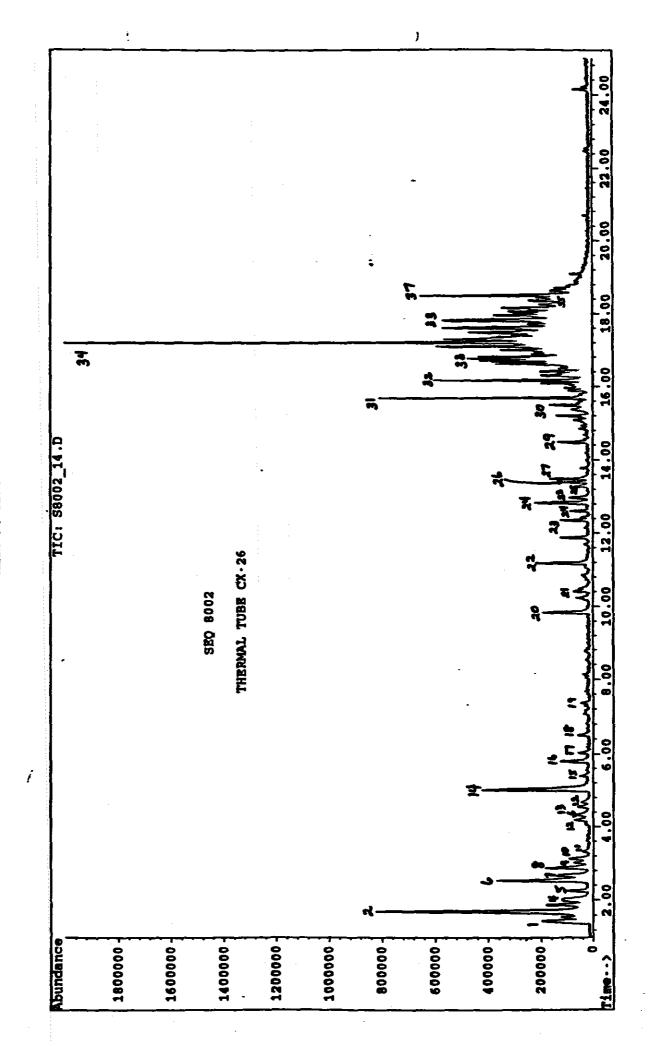
BLOW MOLDING — CAN ASSEMBLY RUBBERMAID, INC. HETA 94-0198



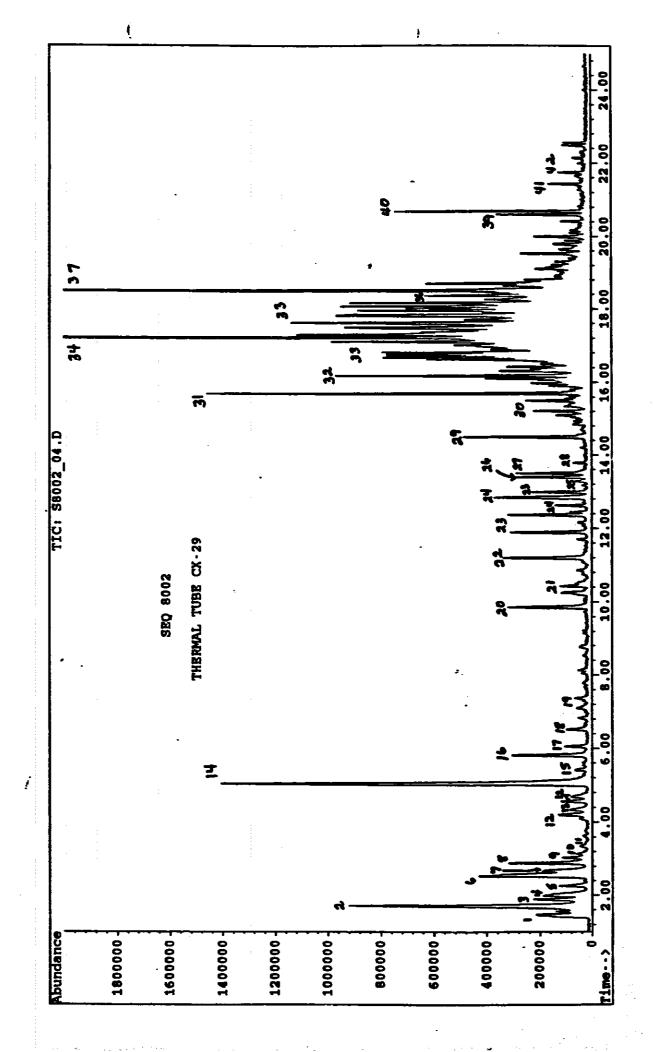
BLOW MOLDING — CAN ASSIMBLY RUBBERMAID, INC.
HETA 94-0198



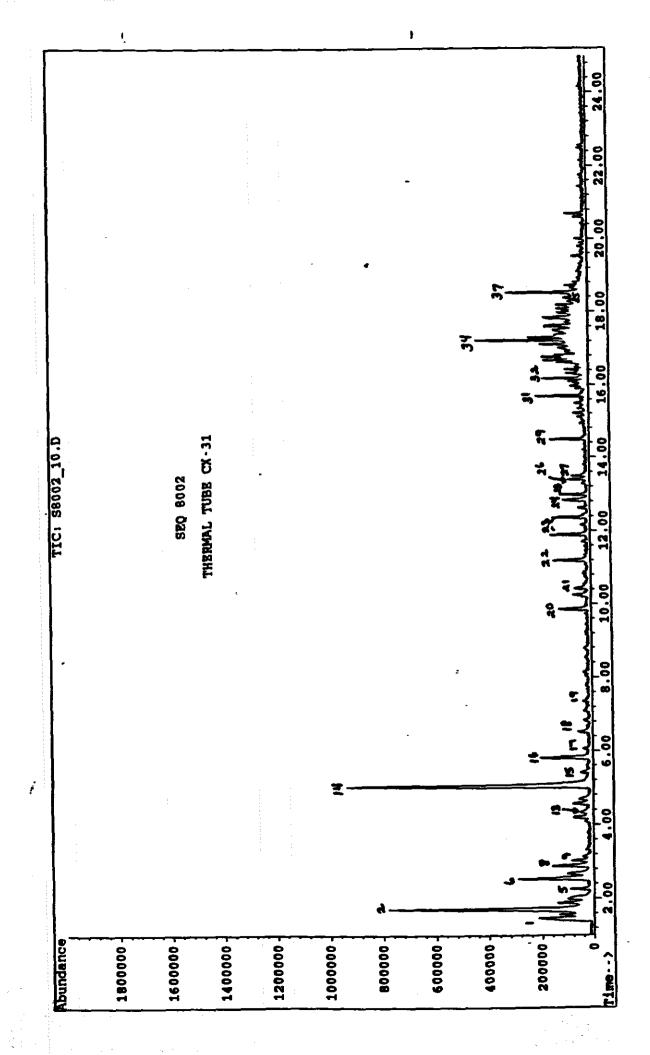
PLASTICS 1 -- BLACK HANDLES PACKING TABLE RUBBERMAID, INC. HETA 94-0198



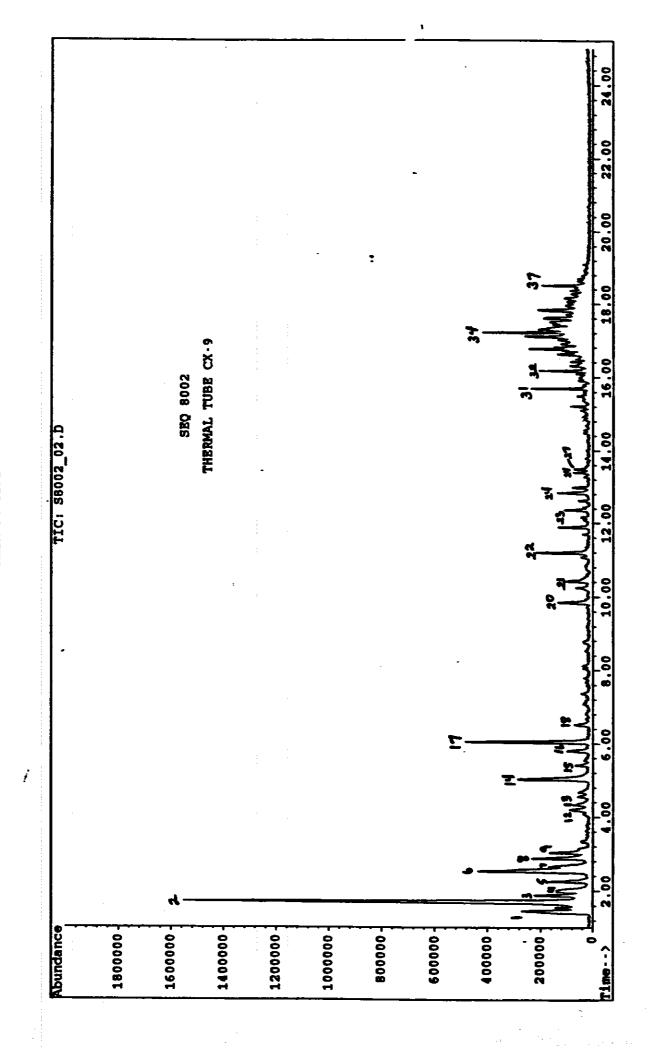
PLASTICS 1 — BLACK HANDLES PACKING TABLE RUBBERMAID, INC. HETA 94-0198



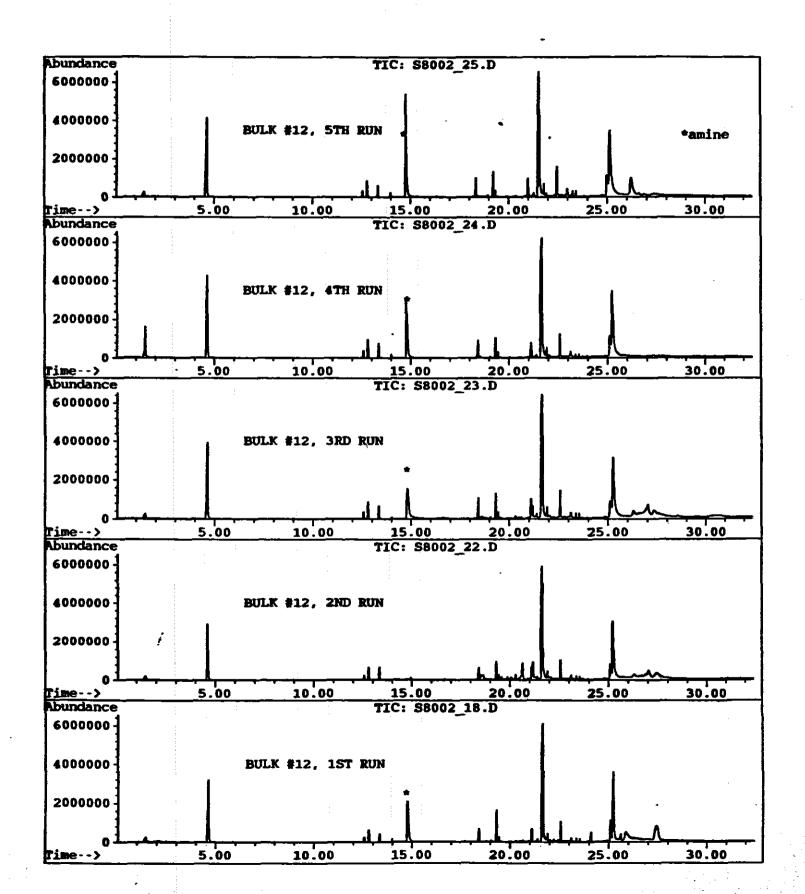
PLASTICS 1 — BLACK HANDLES PACKING TABLE RUBBERMAID, INC. HETA 94-0198



PLASTICS 1 — TEAL HANDLES MOLDING LINE RUBBERMAID, INC. HETA 94-0198



Appendix B



20.00 22.00 24.00 26.00 28.00 30.00 19 11 11 TIC: S8002 23.D 14.00 ethylethyl)phenole possible P compound: 2,6-di-tert-butyl 12.00 800, 5002 800.8, 812 NEATED 215°C FOR 5 MIN. N Abundance 800000 200000 1800000 1600000 1400000 1200000 1000001 600000 400000

IRGANOX B-900 ANTIOXIDANT RUBBERMAID, INC. HETA 94-0198

ţ

18,00 20,00 22,00 24,00 26,00 28.00 ~ TIC: 58002_16.D SEC 8002 BULK #10 HEATED 215°C FOR 5 MIN. Air/co, Butene 100000 200002 600000 1000001 800000 1400000 1200000 Abundance 1800000 1600000

BLACK COLOR PELLETS RUBBERMAID, INC. HETA 94-0198

20.00 22.00 24.00 26.00 28.00 TIC: S8002 20.D 12.00 14.00 16.00 pheno1/ isHadCisHa aliphatics isHadCisHa aliphatics thoxy ethyl bengoate C,H,s/C,H,s aliphatics SEG 8002 BULK #7 HEATED 215°C FOR 5 MIN. imethyloxetene? cycloalkane Methyl pentanol7 :-Butanol Propane Letone entene 9 Abundance 1000001 200000 1800000 1600000 1400000 1200000 800000 000009 400000

BLACK HANDLE VIRGIN MATERIAL RUBBERMAID, INC. HETA 94-0198

ì 18.00 20.00 22.00 24.00 26.00 28.00 • ស TIC: \$8002_17.D SEC 8002 BULK #13 HEATED 215°C FOR 5 MIN. :-Butyl phenol Licosene Decene Abundance 1200000 1800000 1400000 1000001 1600000 800000 000009 400000 200002

BLACK REGRIND RUBBERMAID, INC. HETA 94-0198

Ę 24.00 26.00 28.00 22.00 • 20.00 ហ TIC: S8002 15.D SEC 8002 BULK #14 HEATED 215°C FOR 5 MIN. Air Mitrogen compounds? Tetradecene Hexadecene Octadecene į Dodecene Elcosene Octene 2.00 Abundance 600000 200000 1200000 1000000 800000 400000 1400000 1800000 1600000

TEAL REGRIND RUBBERMAID, INC. HETA 94-0198

20.00 TIC: 88002 21.D methyl furandione. (Citric acid decomposition products?) SEG 8002 BULK #9 HEATED 215°C FOR 5 MIN. ŕ Abundance 0000006 8000000 7000000 0000009 5000000 4000000 300000 2000000 1000001

BLOWING AGENT RUBBERMAID, INC. HETA 94-0198

Appendix C

Report

To

GEIGY CHEMICAL CORPORATION

ΩO

PHOTO-TOXICITY STUDY

Submitted

Ву

Clover Laboratories, Inc.

Philadelphia 1, Pa.

SENSITIZATION

Method:

Twenty-five (25) healthy adult males are used as subjects. The inductive procedure consists of a course of five (5) forty-eight (48) hour exposures with one (1) day in arvals between exposures. If the test agent is non-irritating, it is tested at twenty-five per cent (25%) concentration in petrolatum. Each exposure is to exactly the same site, usually an extremity, which has been irritated by a prior twenty-four (24) hour treatment with five per cent (5%) aqueous solution of sodium lauryl sulfate. If the test agent is intrinsically irritating, it is used at the threshold concentration for irritancy, and the site is not pretreated with sodium lauryl sulfate.

Two (2) weeks after the last exposure, a new skin area is challenged by a forty-eight (48) hour patch test, usually ten per cent (10%) in petrolatum (unless irritancy forbids). The challenge is applied to a normal area pretreated for one (1) hour with sodium lauryl sulfate; this is the provocative challenge test for the detection of marginal states of sensitization. Readings are made for three (3) successive days.

The patch test consists of a 1.5 inch square of non-woven cloth (Webril) to which about 0.75 grams of test agent is applied. It is held to the skin under an occlusive, impermeable dressing of plastic tape (Blenderm - Minnesota Mining and Manufacturing Corporation).

GEIGY INDUSTRIAL CHEMICALS RA 1076 SENSITIZATION STUDY

• •	Sub. #	Age	CHA 48 Hours	LLENGE REACT	PS Hours
្ន	1	23	0	0	0
•	2	32	: : 0	0	0
	3	29 .	0	0	0
:	4	39	0	0	0
•	5	41		0	0 .
	6 · `	21	0	0	0
	7	25	Ö	0	0
	8	. * 3 3	0		0
	9	26	• • • • • • • • • • • • • • • • • • • •	0	o
	10	24	0	0 .	G
	11	31	0	0	0
	12	28	0.	0	0
	13	. 36	0 ,	0	0
	/. 14	22	٥		0
	15 .	29	0	. 0	o
	16	3 5	0	0	C

		CHALLENGE REACTION			
Sub. #	Age	48 Hours	72 Hours	96 Hours	
17	25	• • • • • • • • • • • • • • • • • • • •	0	0 .	
18	31	0	. 0.	ο.	
19	42	. ė	0	0	
20	36	o	0	0	
21	24	. 0	0	0	
22	30	0	0	0	
23	28	0	0	ð	
24	37	• 0	0	G	
25	21	•	0	G	

SUMMARY: No Sensitization.

REPORT TO

CIBA-GEIGY CORPORATION

HUMAN REPEATED INSULT PATCH TEST WITH CODE 35/4/0084/5 AND CODE 335/4/0075/3

JUNE 18, 1975

IBT NO. 636-06615

I. Introduction

Two samples identified as Code 35/4/0084/5 and Code 335/4/0075/3 were received from Ciba-Geigy Corporation for evaluation of their skin irritating and skin sensitizing properties employing 50 human test subjects. The test materials were evaluated as received.

II. Summary

A human repeated insult patch test employing 50 subjects was conducted with 2 materials identified as Code 35/4/0084/5 and Code 335/4/0075/3. The materials were evaluated as received.

Only 3 subjects exhibited reactions during the induction phase of the study. Two of these subjects also showed reactions to the challenge application. Their data are summarized below.

Subject No. 3 (female) exhibited mild erythema with very slight edema (score 2-1) with Code 35/4/0084/5 only, following the ninth induction patch. No reaction was observed, however, after the challenge application.

Subjects Nos. 6 and 21 (females) exhibited delayed severe reactions (scores 4-4) following the ninth induction patch and the challenge application to both test materials. These 2 reactions are indicative of sensitization.

Subject No.21 has known allergies to dust, milk, chocolate, gum arabic, gum tragacanth, gum karaya, molds and food preservatives.

No other reactions (all scores 0) were observed in any of the remaining subjects during the induction or challenge phases.

Respectfully submitted,

INDUSTRIAL BIO-TEST LABORATORIES, INC.

Report prepared by:

Orene Caniel

Joanne Chmiel

Technician

Clinical Evaluations

Report approved by:

Richard J. Palazzolo, N.S.

Technical Klanager

Clinical Evaluations

Robert G. Sanders, Ph.D.

Manager, Clinical Evaluations

jtg

HILL TOP RESEARCH INSTITUTE, INC. Miamiville, Ohio

April 24, 1963

N-61E

REPEATED INSULT PATCH TEST OF RA-1076

For Geigy Industrial Chemicals

ABSTRACT

In a repeated insult patch test completed by 57 human subjects a 0.5% solution of RA-1076 in dimethyl phthalate caused essentially no irritation. A 58th subject became strongly sensitized to this material during the third week of the test and therefore was not challenged.

PURPOSE

To evaluate the irritative potential of the test solution on human skin and to determine whether it would cause sensitization.

TEST MATERIAL

The test material is a white powder labeled RA-1076, received from Geigy Industrial Chemicals on February 25, 1963. The test solution was prepared by dissolving the sample in dimethyl phthalate at a concentration of 0.5 gm per 100 ml.

PROCEDURE

The test patch was a 3/4 x 7/8-inch swatch of Webril moistened with 0.5 ml of the test solution and held to the skin with a Duke Elastoplast Coverlet No. 330. The test patch was applied to the upper arm of each subject. Subjects were instructed to remove the patch 24 hours after application. The patch was applied to the same site each time, unless the severity of reaction made this inadvisable, in which case subsequent applications, if any, were made to an adjacent site. For the challenge duplicate patches were applied, one to the original test site and the second to an area not previously exposed to the test solution.

Test patches were applied and reactions scored on the following schedule.

<u>CA</u>	plicat	ion	Applied .	Scored	Application	Applied	Scored
	1	•	3/4/63	3/6	7	3/18	3/20
	2	•	3/6 .	3/8	3	. 3/20	3/22
	3		3/8	. 3/11	9	3/22	3/25
:	4		3/11	3/13	0.A	4/8	4/10
	5	•	3/13	3/15	. O' ,A'	•	4/12
	6	•	3/15 .	3/18		•	

. 0,A · Challenge on criginal (0) and fresh (A) sites. -0',A' Second scoring of chillenge. For the serial applications Subjects 1 - 10 followed a schedule one week earlier than that for the main group. All subjects were challenged on the same date. For convenience of study the records for Subjects 1 - 10 are shown in the data table as though they had followed the same so redule as the remainder.

Reactions were scored on the following scale:

- 0 No evidence of irritation
- 1 Slight erythema
- 2 Marked erythema
- 3 Erythema and papules
- E Erythema and edema
- 4 · Erythema, edema and paules
- 5 · Vesicular eruption
- 6. Strong reaction extending beyond test area .

Sixty-three subjects enrolled in the test. Subjects were furnished by the St. Clare Church, Cincinnati, Ohio. Subjects 18, 20, 58, 61 and 62 discontinued attending for reasons irrelevant to the test, after the 7th, 9th, 5th, 2d, and 2d sessions, respectively. None of these subjects exhibited any significant degree of reaction during the time they were under observation. Subject 50 was excused from further attendance after the 10th session because of excessive reaction to the test material. The sex and age distributions of the 58 subjects are shown below. All subjects were of the Caucasian race.

Age Range	<u> Kale</u>	Female	•
16-19 } 20-29 30-39	7	6	
20-29	0 ^	5	
30-39	• 4	ġ	
40-49	3	10	•
50-59	ĺ	7	
60-69	Ö.	· • •	
72-73	0	2_	
	15	43, Tota	1 = 58

rebults

Please refer to Table I for individual reaction scores and group totals at each scoring.

Subject 50, a 16-year-old girl, exhibited on 3/25 a grade 6 reaction centered on the test site with an area of edema and induration extending several inches in each direction. During the following week this became still more severe, involving most of the arm, with vesicles over some areas. She responded

to topical and internal medication, and when last seen on 4/10 exhibited only some residual erythema on and around the test site. She had reported an earlier dermatitis following use of Cuticura, otherwise her dermatological history was negative. This subject was not challenged.

CONCLUSION

Under the conditions of this test 0.5t RA-1076 in dimethyl phthalate causes little irritation. One of 58 subjects became sensitive to the test material during the test.

Respectfully submitted,

HILL TOP RESEARCH INSTITUTE, INC.

Join R. Elsea, Ph.D. Director of Toxicology

Farry L. Rubenkoenig Technical Director

buiton to Hein

Ashton L. Welsh, M.D., M.S., D.A.B.D.S. Dermatologist

REPORT TO

CIBA-GEIGY CORPORATION

HUMAN REPEATED INSULT PATCH TEST WITH SEVEN EXPERIMENTAL SAMPLES

APRIL 10, 1975

IBT NO. 636-06407

I. Introduction

Seven experimental samples were received from CIBA-GEIGY Corporation for evaluation of their skin irritating and skin sensitizing properties employing 50 human test subjects. The test materials were identified as follows:

Pergopak M
Paper treated with Pergopak M
Fat 65'046/A
CHA 1024 Batch EP-2
CHA 1024 Batch 9/4/0208/0
CGL-100 Batch EP-105
Irganox 1076 Batch 5/4/0328/0

II. Summary

A human repeated insult patch test utilizing 50 human subjects was conducted with 7 experimental samples. The test materials were identified as follows:

Perkopak M

Paper treated with Pergopak M

Fat 65'046/A

CHA 1024 Batch EP-2

CHA 1024 Batch 9/4/0208/0

CGL-100 Batch EP105

Irganox 1076 Batch 5/4/0328/0

The test materials were evaluated as received except for CGL-100 Batch EP-105, which was used neat for the first application, at a 10 percent concentration in corn oil for applications 2 and 3, and at a 1 percent concentration in corn oil for the balance of the study.

A summary of the reaction scores during the induction applications of CGL-100 Batch EP-105 is presented below.

No. of Reactions/ No. of No. of **Patches** No. of Reactions with Scores of: Material Conc.(%) Reactors Applied CGL-100 Neat 31 31/50 19 Batch EP-105 10 44 61/84 2 13 15 3 1 2 2/299 297 0

CGL-100 Batch EP-105 at full strength and at a concentration of 10 percent in corn oil would be considered a primary skin irritant. At a concentration of 1 percent in corn oil the test material showed only minimal dermal irritation. No sensitization reactions were noted following the challenge sp-plication of this material. The other 6 test materials produced no irritation during the induction phase and no sensitization following the challenge application.

Respectfully submitted,

INDUSTRIAL BIO-TEST LABORATORIES, INC.

Report prepared by:

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Clinical Evaluations

Report approved by:

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Technical Manager

Clinical Evaluations

Robert G. Sanders, Ph.D.

Manager, Clinical Evaluations

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